

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Entresto (Sacubitril/Valsartan) Patent Litigation

C.A. No. 20-2930-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

V.

MSN PHARMACEUTICALS INC., MSN
LABORATORIES PRIVATE LIMITED,
MSN LIFE SCIENCES PRIVATE
LIMITED, NANJING NORATECH
PHARMACEUTICAL CO., LIMITED,
Defendants.

C.A. No. 22-1395-RGA

**LETTER TO THE HONORABLE RICHARD G. ANDREWS ON
BEHALF OF DEFENDANTS IN RESPONSE TO THE
COURT’S NOVEMBER 8, 2024 MEMORANDUM ORDER**

Dear Judge Andrews,

Defendants provide this information in response to the Court's November 8, 2024 Memorandum Order responding to Novartis's argument that Dr. McCreery "is not a POSA because he does not have 'two or more years of experience with solid forms of pharmaceutical compounds.'" (D.I. 1625, at 6 n.6.) Dr. McCreery clearly possesses the requisite training and experience.

Novartis misquotes Defendants' POSA definition and omits key language. (D.I. 1557, at 4.) Dr. McCreery is a POSA because he has "(1) a Ph.D. in chemistry...; and (2) two or more years of experience with solid forms of pharmaceutical compounds, *such as synthesizing, crystallizing, and characterizing solid forms of molecular pharmaceutical compounds, including experience in small-molecule characterization techniques (e.g.,..., Raman, etc.)*." (D.I. 1558-1, Ex. 3 at ¶ 22 (Defendants' full definition of a POSA) (emphasis added).)

Dr. McCreery is a Ph.D. in Analytical Chemistry from the University of Kansas, and taught chemistry for over 50 years at Ohio State University and University of Alberta. He has far more than two years of experience with solid forms of pharmaceutical compounds that includes synthesizing, crystallizing, and characterizing such compounds, including *decades* of experience in the *small-molecule characterization technique at issue in this case—Raman spectroscopy*. (Ex. A at ¶ 9-11, 101.) Dr. McCreery stated that he "exceed[s] that level of education and experience, did so in 2005-2006 and was working in the relevant field before, during, and after 2005–2006 along with others who generally fit the foregoing description of a POSA." (*Id.* at ¶ 22.) At his deposition, Dr. McCreery testified that his "original dozen papers were about chlorpromazine, which is the active ingredient in Thorazine," published "several early papers in the Journal of Medicinal Chemistry," and that "[p]robably the *first ten years* of [his] career was mainly on pharmaceutical materials, because [his] Ph.D. involved neurosciences, and [he] was interested in, particularly, heterocyclic antidepressants and antipsychotics." (Ex. B at 20:10-21:4; *id.* at 22:8-23:9.) He further testified that he conducted a study of over 300 pharmaceutical compounds involving Raman spectroscopy at the behest of the FDA drug lab, which involved "several months of lab work" and "established that Raman was very good for distinguishing different white *solids*...inside brown vials." (*Id.* at 24:10-27:17; Ex. C.) Additionally, *the* seminal textbook authored by Dr. McCreery, "Raman Spectroscopy for Chemical Analysis," discusses numerous pharmaceutical applications. (Ex. D at 86, 90, 102, 112-113, 293, 302-304, 323-326, 355-364.)

The evidence cited by Novartis is scarce. Novartis states that Dr. McCreery has not studied any supramolecular complexes—not required of a POSA here; and that he did not identify pharmaceuticals as one of his research interests—an argument that is easily contradicted by his testimony, as discussed above. (D.I. 1557, at 4.) Based on his expertise in Raman spectroscopy, he concludes that Dr. Park's data shows that "neither Raman spectroscopy nor Raman imaging can be used to show the presence of an amorphous TVS." (D.I. 1558-1, Ex. 6 at ¶ 123.) Your Honor correctly notes that Dr. McCreery is not offering an opinion on non-infringement and, therefore, does not require the "*perspective of a skilled artisan*" from the "*vantage point of an ordinarily skilled artisan*." *Kyocera Senco Indus. Tools Inc., v. ITC*, 22 F.4th 1369, 1376-77 (Fed Cir. 2022). He is criticizing Dr. Park's work—who is not offering any opinion on infringement. While Dr. McCreery meets the definition of a POSA, his opinion is also highly relevant because it is largely focused on Raman spectroscopy and instrumentation—an area in which he possesses specialized expertise (and Dr. Park does not) (D.I. 1558-1, Ex. 6 at ¶ 20 (defendants' POSA definition: "a POSA may have consulted with individuals having *specialized expertise*, for example...")), and basic knowledge of chemistry expected of every chemist, whether a POSA or not.

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Dated: November 13, 2024